

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

REC'D 23 AUG 2005

WIPO

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PA1365 PCT	<b>FOR FURTHER ACTION</b>	
See Form PCT/IPEA/416		
International application No. PCT/IE2004/000057	International filing date (day/month/year) 16.04.2004	Priority date (day/month/year) 17.04.2003
International Patent Classification (IPC) or national classification and IPC A61L31/10, A61L29/08		
Applicant MEDTRONIC VASCULAR CONNAUGHT		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> <i>(sent to the applicant and to the International Bureau) a total of sheets, as follows:</i></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <i>sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</i></li> <li><input type="checkbox"/> <i>sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</i></li> </ul> <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</i></p>		
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the opinion</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input type="checkbox"/> Box No. VI Certain documents cited</li> <li><input type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>		

Date of submission of the demand 08.11.2004	Date of completion of this report 24.08.2005
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Thornton, S  Telephone No. +31 70 340-



# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/IE2004/000057

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
    - international search (under Rules 12.3 and 23.1(b))
    - publication of the international application (under Rule 12.4)
    - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements\* of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

### Description, Pages

1-16 as originally filed

### Claims, Numbers

1-14 as originally filed

### Drawings, Sheets

1/4-4/4 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

- The amendments have resulted in the cancellation of:
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):
- This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/IE2004/000057

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	1-14
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-14
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-14
	No:	Claims	

**2. Citations and explanations (Rule 70.7):**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.  
**PCT/IE2004/000057**

**Re Item V.**

The following documents are referred to in this communication:

- D1 : US 5 005 287 A
- D2 : US 4 373 009 A
- D3 : WO 98/58988 A
- D4 : WO 00/30696 A

**Clarity**

The application does not meet the requirements of Article 6 PCT, because claims 1,6,8,12 are not clear. The statement "at least two polymeric species of differing molecular weights" is not clear as every polymer comprises at least two polymeric species of differing molecular weights. The polymers in question have different "weight average molecular weights" and in this communication the statement "at least two polymeric species of differing molecular weights" has been understood to mean at least two polymers of differing weight average molecular weights.

**Novelty**

D1 discloses a hydrophilic coating, e.g. for a razor, that comprises a water-soluble polymer or copolymer of polyvinyl pyrrolidone (PVP), at least one polymerisable vinyl monomer and a photoinitiator (see D1, column 2, line 36 to column 3, line 12; column 3, line 58 to column 4, line 14; examples; claims).

D2 discloses a coating for biomedical devices, e.g. catheters comprising polymers that can be produced using reactive diluents, e.g. N-vinyl pyrrolidone in the presence of benzophenone which causes the polymer to crosslink under ultraviolet light to give hydrophilic coatings (see D2, column 4, line 38-47; examples; claims).

D3 discloses a hydrophilic coating for biomedical devices comprising, e.g. PVP of two molecular weights, benzophenone, an acrylate prepolymer and a solvent (see D3, examples 7,8; claims).

D4 discloses a hydrophilic coating for biomedical devices comprising PVP which can also by UV irradiation be sterilised (see D4, page 6, line 23 to page 7, line 4; claims).

**INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY  
(SEPARATE SHEET)**

International application No.  
PCT/IE2004/000057

D1-D4 do not disclose a coating formulation comprising at least two polymers of different weight average molecular weights, an unsaturated hydrophilic monomer and a UV activatable compound as disclosed in independent claims 1,12. The subject-matter of claims 1,12 is therefore new in the sense of Article 33(2) PCT.

**Inventive Step**

The objective problem to be solved can be regarded as to provide improved hydrophilic coatings for biomedical devices which facilitates the passage of the coated device.

Document D1, which is considered to represent the most relevant state of the art, discloses a hydrophilic coating, e.g. for a razor, that comprises a water-soluble polymer or copolymer of polyvinyl pyrrolidone (PVP), at least one polymerisable vinyl monomer and a photoinitiator (see D1, column 2, line 36 to column 3, line 12; column 3, line 58 to column 4, line 14; examples; claims) from which the subject-matter of claims 1,12 differs in that the coating formulation comprises at least two (i.e. a blend of) polymers of different weight average molecular weights. The effect of having such a blend is "to optimise the hydrophilicity of the coating when wetted (cf. figure 1). The final coating on the surface of the medical device comprising an interpenetrating network has polymeric species of different lengths extending away from it which provides a means by which water may be trapped between the polymeric species when the surface is wetted, lending it hydrophilic and lubricious characteristics" (see present application, page 8, lines 1-20). It would not be obvious for a person skilled in the art from the teachings of D1 nor in combination with D2, D3 nor D4 to arrive at the solution proposed in the subject-matter of independent claims 1,12 of a coating formulation comprising at least two polymers of different weight average molecular weights, an unsaturated hydrophilic monomer and a UV activatable compound that would give rise to such an effect. Therefore, the solution proposed in the subject-matter of claims 1-14 is considered to involve an inventive step in the sense of Article 33(3).